HYPERACCELERATED AWARD/MECHANISMS IN IMMUNOMODULATION TRIALS

Release Date: November 24, 1999

RFA: AI-00-005

National Institute of Allergy and Infectious Diseases
National Institute on Aging
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
National Heart, Lung and Blood Institute
National Institute of Neurological Disorders and Stroke
Office of Research on Women's Health

Letter of Intent Receipt Date: One month prior to application receipt date.
Application Receipt Date: Applications will be accepted MONTHLY on the 9th of each month.

THIS RFA USES "MODULAR GRANT" CONCEPT. THIS RFA INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING AN APPLICATION IN RESPONSE TO THIS RFA.

PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID), the National Institute on Aging (NIA), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Neurological Disorders and Stroke (NINDS), and the Office of Research on Women's Health (ORWH) of the National Institutes of Health (NIH) invite investigator-initiated research applications for mechanistic studies in clinical trials of immunomodulatory interventions for immune system mediated diseases, including, but not limited to, asthma and allergy, graft failure in solid organ, tissue, cell and stem cell transplantation, and autoimmune diseases. Specifically, this Request for Applications (RFA) is a continuation and modification of RFA AI-98-006. It focuses on the inclusion of patients and utilization of patient samples for the evaluation of immunologic and other relevant parameters to facilitate the study and definition of immunological mechanisms underlying the intervention, the mechanisms of disease pathogenesis, surrogate/biomarkers markers of disease activity and therapeutic effect, and mechanisms of

human immunologic function. The parent or core clinical trial must have independent financial support and will NOT receive support under this RFA. Proposed mechanistic studies associated with clinical trials supported by industry are particularly encouraged but clinical trials supported by any source, public or private, are eligible.

In order to review and confer awards to applications received in response to this RFA in a timely fashion without delay of the parent or core clinical trial, NIAID has developed a pilot project in collaboration with the Center for Scientific Review (CSR): NIAID/CSR PILOT OF HYPERACCELERATED REVIEW/AWARD. All applications responding to this RFA will be subject to this hyperaccelerated review/award process. Highly meritorious applications selected for funding under this RFA will receive their awards thirteen weeks after the application receipt date. Holidays and other circumstances may alter this schedule slightly.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of “Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, HYPERACCELERATED AWARD/MECHANISMS IN IMMUNOMODULATION TRIALS, is related to the priority area(s) of immunization and infectious diseases and diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" at http://odphp.osophs.dhhs.gov/pubs/hp2000.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations; public and private institutions, such as universities, colleges, hospitals, laboratories, units of State and local governments; and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

MECHANISM OF SUPPORT

The mechanism of support will be the individual research project grant (R01). The total requested project period for an application submitted in response to this RFA may not exceed four years. Some sponsoring Institutes may administratively limit the duration of award. Applicants for the R01 mechanism must not exceed a first-year limit of $250,000 direct costs.

Modular grant procedures should be used.

Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant.

Specific application instructions have been modified to reflect “MODULAR GRANT” and “JUST-IN-TIME” streamlining efforts being examined by the NIH. Complete and detailed instructions and information on Modular Grant applications can be found at http://grants.nih.gov/grants/funding/modular/modular.htm

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for all awards made under this RFA in FY 2000 will be $1,800,000. In Fiscal Year 1999 seven awards were made. The usual PHS policies governing grants administration and management will apply. Although this program is provided for in the financial plans of the participating institutes, awards pursuant to this RFA are contingent upon the availability of funds for this purpose and the receipt of a sufficient number of applications of high scientific merit. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years and availability of funds.

RESEARCH OBJECTIVES

Background

In December 1996, NIAID convened a workshop at which leading basic and clinical immunologists discussed the role the NIH should play in current and projected clinical trials for various immune mediated diseases. It was considered likely that clinical trials of many new immunologic interventions would be supported by the pharmaceutical/biotechnology industry. However, gaps in both knowledge and in research effort were identified which represent opportunities for the NIH to contribute to progress in this area.

There was agreement that the mechanisms underlying immunologic interventions are poorly understood even in cases where efficacy has been shown (e.g., allergen immunotherapy and IFN Beta treatment for multiple sclerosis.) In addition, clinical trials supported by industry and other sources including NIH often do not include studies of underlying mechanisms. There was

consensus that high priority should be given to the utilization of patient samples from clinical trials in immunologic diseases for studies of the basic underlying mechanisms of therapeutic effect, immunologic function, and disease pathogenesis.

There was also agreement that the usual time required for grant review and funding is often incompatible with the time line of a clinical trial. Specifically, when a clinical protocol is finalized (which is required for applications submitted under this RFA), investigators are often ready to begin as soon as Institutional Review Board approval is obtained. NIAID was encouraged to develop a means of responding rapidly to opportunities to study underlying mechanisms in order to facilitate collaborations with industry-supported clinical trials.

These recommendations were strongly supported by a large number of investigators who participated in NIAID focus groups in the winter/spring of 1997. The RFA AI-98-006 and the NIAID/CSR PILOT OF HYPERACCELERATED REVIEW/AWARD were developed in order to implement these recommendations and exploit the research opportunities identified. Based on the successful implementation of RFA AI-98-006 and the Pilot, the current RFA is being issued to continue this effort.

Research Objectives and Scope

The objective of this RFA is to support mechanistic research studies in clinical trials of immuno-modulatory interventions for immune system mediated diseases, including asthma and allergy, graft failure in solid organ and stem cell transplantation, and autoimmune diseases. Specifically, the goal is to utilize patients and patient materials from such trials for the evaluation of immunologic and other relevant parameters in order to study the underlying mechanisms of the intervention, the mechanisms of disease pathogenesis, surrogate markers of disease activity and therapeutic effect, and mechanisms of human immunologic function. Such studies are not part of the parent or core clinical trial, and are commonly referred to as substudies or ancillary studies. The parent or core clinical trial must have independent financial support and will NOT receive support under this RFA. Clinical trials supported by any source, public or private, are eligible. Clinical trials of any phase (i.e. I-IV) are eligible. Examples of relevant research include, but are not limited to, the following:

o Quantitation of disease-related, autoreactive or alloreactive lymphocytes using methods such as MHC/peptide tetramers, chimeric antibodies, or very early activation antigens.

o Analysis of autoreactive or alloreactive cells by PCR for expression of genes implicated in immunity or inflammation, or by FACS for cell surface markers that identify functions (e.g., cytokine receptors that distinguish TH1 from TH2 or chemokine receptors or integrins that indicate preferential patterns of homing).

o Assessment of reagents that can identify newly recognized populations of regulatory T cells (e.g., Valpha24JalphaQ bearing invariant T cells) which appear to be altered in autoimmune disease.

o Identification and evaluation of cytokine and cytokine receptor polymorphisms and analysis for genetic linkage to disease.

o Use of high throughput technologies (e.g. chip technology using expressed sequence tags) to identify and evaluate genes activated in disease sites.

o Identification of useful surrogate markers by correlation of the above parameters with disease activity and/or response to intervention.

o Comparison of samples from peripheral blood with those from sites of disease, i.e., do peripheral blood samples provide useful information?

o Assessment for the presence of molecular evidence (e.g. using PCR probes) of potential causative environmental agents.

The areas outlined above are not intended to be all-inclusive.

NOTE: Clinical trials in infectious diseases, which involve the immune system (e.g. AIDS and Lyme Disease), are NOT eligible for this RFA.

SPECIAL REQUIREMENTS

In addition to yearly progress reports, the Principal Investigators of grants funded under this RFA will provide brief (1-2 pages) summary reports of the outcomes of the research at the conclusion of the funding period and one year later. The reports will summarize the major scientific knowledge gained and identify other substantive outcomes such as publications, patents, and new grants, contracts, or research studies based on this mechanistic research.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects of the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43)

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994 which is available via the WWW at: http://grants.nih.gov/grants/guide/notice-files/not94-100.html

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html

Investigators may obtain copies of these policies from these sources or from the program staff (listed in INQUIRIES below) who may also provide additional relevant information concerning the policy.

LETTER OF INTENT

Prospective applicants are asked to submit, one month prior to the application receipt date, a letter of intent that includes: a descriptive title of the overall proposed research; the name, address and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions and the number and title of this RFA.

Although the letter of intent is not required, is not binding, does not commit the sender to submit an application, and does not enter into the review of subsequent applications, the information that it contains allows review to estimate the potential review workload and to avoid conflict of interest in the review. The Letter of Intent is to be sent to Dr. Zimmerman at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applicants are strongly encouraged to contact program staff listed under INQUIRES with any questions regarding the responsiveness of their proposed project to the goals of this RFA.

Applications are to be submitted on the grant application for PHS 398 (rev. 4/98). These forms are available at most institutional offices of sponsored research; from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: grantsinfo@nih.gov; and on the internet at http://grants.nih.gov/grants/funding/phs398/phs398.html

For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number “AI-00-005” and the words "HYPERACCELERATED AWARD/MECHANISMS IN IMMUNMODULATORY TRIALS" must be entered on the face page.

Applications must be received by the 9th of each month. Applications which are received after the 9th will automatically be processed the following month. Applications not received as a single package (See Special Instructions Section below) on the receipt date or not conforming to the instructions contained in PHS 398 (rev. 4/98) Application Kit (as modified in, and superseded by, the special instructions below, for the purposes of this RFA), will be judged non-responsive and will be returned to the applicant.

The RFA label available in the application form PHS 398 must be affixed to the bottom of the face page. The RFA label and line 2 of the application must indicate the RFA number. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. The sample RFA label available at: http://grants.nih.gov/grants/funding/phs398/label-bk.pdf has been modified to allow for this change. Please note this is in pdf format.

If the application submitted in response to this RFA is substantially similar to a grant application already submitted to the NIH for review, but that has not yet been reviewed, the applicant will be

asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. Therefore, an application that is essentially identical to one that has already been reviewed cannot be submitted in response to this RFA. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

Submit a signed, typewritten original of the application, including the checklist; five signed, exact, single-sided photocopies; and five sets of appendix material in one package to:

PLEASE NOTE THAT THIS ADDRESSES IS DIFFERENT FROM THE INSTRUCTIONS IN THE PHS 398 APPLICATION KIT AND FAILURE TO COMPLY WILL RESULT IN DEFERRAL OF REVIEW.

Dr. Suzanne Fisher
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 2030 - MSC 7720
Bethesda, MD 20892-7720
Bethesda, MD 20817 (for express mail or courier service)

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC Program Director or Principal Investigator should be included with the application.

SPECIAL INSTRUCTIONS FOR COMPLETION OF APPLICATIONS IN RESPONSE TO THIS RFA

The research plan in the application should be limited to 15 pages. The research plan includes specific aims, background and significance, preliminary studies, and research design and methods (Sections A to D). In the research plan, include a justification for why the proposed studies require the use of patients in this clinical trial as opposed to using patients with the same disease state but not in a trial.

Methods of data analysis and power calculations must be included. Include a justification for the required sample size. A restatement of the sample size calculations from the parent clinical trial

is insufficient. If appropriate to your application, discuss whether it is necessary to perform the mechanistic studies on all patients enrolled in the parent trial or whether a sub-sample would be sufficient. There must be a discussion of the statistical procedures that will be used to analyze the data. The manner in which immunological parameters will be related to the clinical outcomes in the main study should also be discussed.

The protocol and the investigators' brochure for the parent or core clinical trial should be included with the application as part of the human subjects' section. Inclusion of the complete clinical protocol within the PHS 398 grant application is intended to simplify the application process by eliminating the need to duplicate protocol details in the Research Plan section. Informed Consent form(s) must also be included as part of this section. While drafts of the consent forms at participating sites are not required, it would be useful to include them if they are available. NIH will treat as confidential any scientific, preclinical, clinical, or formulation data and information that the sponsor deems to be proprietary and confidential.

Institutional Review Board (IRB) approval for both the parent or core clinical trial and the mechanistic studies must be submitted if it is available, but must be submitted prior to award.

Amended applications will be accepted for Hyperaccelerated Review/Award ONLY if invited by NIH. Applicants with minor or easily corrected problems will be invited to submit an abbreviated amendment (5 page limit and one time only) which directly addresses the questions and concerns raised in the initial review.

In order to ensure coordination between the mechanistic studies and the parent or core clinical trial, the principal investigator and the sponsor of the parent or core clinical trial must provide written agreement for the conduct of the mechanistic studies as presented in the application.

Prior to award, the applicant must provide to the funding institute a memorandum of understanding signed by the applicant, an appropriate representative of the applicant institution, the principal investigator of the parent or core clinical trial, and an appropriate representative of the sponsor of the parent or core clinical trial. This memorandum will indicate agreement and will outline the specifics of the agreement for the following areas: 1) data from the mechanistic studies (including ownership, analysis, access, and release), 2) access to the data from the parent or core clinical trial (how/when) which is needed to analyze the mechanistic studies, including procedures for prevention of unblinding of the parent trial, 3) documentation of quality assurance procedures for both the parent trial and the mechanistic studies, and documentation of Data Safety Monitoring procedures for the parent trial, especially for efficacy trials,

4) ownership of intellectual property developed during the mechanistic studies, and 5) publication of the results of the mechanistic studies.

MODULAR APPLICATION DETAILS:

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and Institute staff. The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants, with the modifications noted below.

BUDGET INSTRUCTIONS

Modular Grant applications will request direct costs in $25,000 modules.
R01s may request a maximum of $250,000 direct costs per year.

For modular grant applications, the total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

PHS 398

o FACE PAGE: Items 7a and 7b should be completed, indicating Direct Costs (in $25,000 increments up to a maximum of $250,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Prepare a Modular Grant Budget Narrative page. (See http://grants.nih.gov/grants/funding/modular/modular.htm for sample pages.) At the top of the page, enter the total direct costs requested for each year. This is not a Form page.

o Under Personnel, List key project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided. However, the applicant should use the NIH appropriation language salary cap and the NIH policy for graduate student compensation in developing the budget request.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount. Include the Letter of Intent to establish a consortium.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at: http://grants.nih.gov/grants/funding/modular/modular.htm

- Complete the educational block at the top of the form page;
- List position(s) and any honors;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years.
- List selected peer-reviewed publications, with full citations;

o CHECKLIST - This page should be completed and submitted with the application. If the facilities and administration (F&A) rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

o The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by a Scientific Review Group (SRG) established for the NIAID/CSR PILOT OF HYPERACCELERATED REVIEW/AWARD and convened in accordance with NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique, will be discussed by the SRG, assigned a priority score, and receive a second level review by the National Advisory Council of the assigned Institutes. Once a norm is established for the SRG, only those applications deemed to have the highest scientific merit may be discussed.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. The reviewers will comment on the following aspects of the application in their written critiques in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.
Each of these criteria will be addressed and considered by the reviewers in assigning the overall score weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

2. Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation. Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

4. Investigator. Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

5. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

The initial review group will also examine: the appropriateness of proposed project budget and duration; the adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research and plans for the recruitment and retention of subjects; adequacy of plans for including children as appropriate for the scientific goals of the research; the provisions for the protection of human and animal subjects; and the safety of the research environment.

AWARD CRITERIA

Funding decisions will be made on the basis of scientific and technical merit as determined by peer review, program balance, and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic (research scope and eligibility) issues to:

Stephen M. Rose, Ph.D.
Chief, Genetics and Transplantation Branch
Division of Allergy, Immunology and Transplantation
National Institute of Allergy and Infectious Diseases
NIH
6700-B Rockledge Drive Room 5130
Bethesda, MD 20892-7640
301.496.5598 voice
301.402.2571 fax

SRose@niaid.nih.gov

Barbara Mittleman, M.D.
Immunobiology of Aging
Biology of Aging Program
National Institute on Aging
Gateway, 2C231
7200 Wisconsin Avenue
Bethesda, MD 20892-9205
301.496.6402 voice
301.402.0010 fax
mittlemb@exmur.nia.nih.gov

Susana A. Serrate-Sztein, M.D.
Rheumatic Diseases Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-25E, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-5032
FAX: (301) 480-4543
Email: szteins@exchange.nih.gov

Joan T. Harmon, Ph.D.
Diabetes Research Section
National Institute of Diabetes and Digestive and Kidney Disease
45 Center Drive, Room 5AN-18G, MSC 6600
Bethesda, MD 20892-6600
Telephone: (301) 594-8808
FAX: (301) 480-3503
Email: jh90u@nih.gov

James Kiley, Ph.D.
Director, Airway Biology and Disease Program
Division of Lung Diseases
National Heart, Lung, and Blood Institute
6701 Rockledge Drive MSC 7952
Bethesda, MD 20892-7952

Telephone: 301-435-0202
FAX: 301-480-3557
E-Mail: kileyj@nih.gov

A. P. Kerza-Kwiatecki, Ph.D.
Program Officer, DCIID
National Institute of Neurological Disorders and Stroke
Federal Building, Room 504
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: 301-496-1431
FAX: 301-402-2060
E-Mail: ak45w@nih.gov

Direct inquiries regarding review issues and special instructions for application preparation to:

Eugene M. Zimmerman, Ph.D.
Scientific Review Administrator
SSS-J Study Section
Center for Scientific Review, NIH
Room 4202, RKLII Building, MSC 7812
6701 Rockledge Drive
Bethesda, MD 20892-7812 (20817 for couriers)
Telephone: 301-435-1220
FAX: 301-480-4042
E-Mail: gz16t@nih.gov

Direct inquiries regarding fiscal matters to:

Sharie Bernard
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B21
6003 Executive Boulevard
Bethesda, MD 20892-7610
Telephone: 301-402-5540
FAX: 301-480-3780

E-mail: sb34k@nih.gov

Schedule

Letter of Intent Receipt Date: One month prior to application receipt date
Application receipt date: 9th of each month.
Earliest award date: 13 weeks after receipt of application

AUTHORITY AND REGULATIONS

This program is supported under authorization of the Public Health Service Act, Sec. 301 (c), Public Law 78-410, as amended. The Catalogue of Federal Domestic Assistance Citations are No. 93.855 - Immunology, Allergy, and Transplantation Research, No. 93.853, No. 93.838, No. 93.846 –Aging, No.93.866 - Arthritis, Musculoskeletal and Skin Diseases Research, and No. 93.847 - Diabetes, Endocrinology and Metabolism Research. Awards will be administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems review.

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, and portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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